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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,239	07/17/2003	Anthony L. Fitzhugh	14364.99	8121
28390	7590	07/22/2005	EXAMINER	
MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/623,239

Applicant(s)

FITZHUGH ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03/8/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-26 and 33-44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 03/18/05. Claims 1-26 and 33-44 are pending.

#### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 1-26, 33 and 35-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicants' argument with respect to "highly cross-linked" and "extremely hydrophobic" is persuasive. Claim 33 has been amended to state that the method step comprises providing ... and administering.

However, claim 34, which is directed to a method for preventing blood coagulation, does not prescribe how the preventing takes place. "Blending or copolymerizing tubing with highly cross-linked, extremely hydrophobic biocompatible polydiazoniumdiolated polymers" appears not to be the method by which coagulation is prevented or inhibited or treated.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting or treating blood coagulation, does not reasonably provide enablement for preventing blood coagulation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the

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claims as it regards to preventing coagulation. The standard for “preventing” or “prevent” or “prevention” is high and preventing or prevention is to stop the event/coagulation from happening all the time before the incidence of coagulation would occur and reliable prediction of the occurrence and to successfully administer a product/device to stop the incidence of the coagulation from happening. There is no data showing prevention/preventing.

*Claim Rejections - 35 USC § 102*

4. Claims 1, 2, 5 and 23-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pulfer et al. (Incorporation of Nitric Oxide-Releasing Crosslinked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189).

Applicants argue that Pulfer does not teach highly cross-linked and extremely hydrophobic nitric oxide releasing biocompatible polydiazoniumdiolated polyamine-functionalized polymers and that Pulfer discloses cross-linked polyethyleneimine microspheres that are derivatized with Nonates and the No-releasing microspheres are incorporated into the pores of the vascular graft.

5. Applicants' arguments filed 03/18/05 have been fully considered but they are not persuasive.

“Highly cross-linked” and “extremely hydrophobic” are relative terms that read of the cross-linked and hydrophobic polymer of the prior art. Pulfer discloses cross-linked and hydrophobic polymer.

***Claim Rejections - 35 USC § 103***

6. Claims 3, 4, 6-22 and 33-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pulfer et al. (Incorporation of Nitric Oxide-Releasing Crosslinked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189).

Applicants argue that Pulfer does not disclose “highly cross-linked” and “extremely hydrophobic nitric oxide releasing polymer.”

7. Applicants' arguments filed 03/18/05 have been fully considered but they are not persuasive.

Highly cross-linked” and “extremely hydrophobic” are relative terms that read of the cross-linked and hydrophobic polymer of the prior art. Pulfer discloses cross-linked and hydrophobic polymer. Regarding the pore size of the beads, there is no demonstration that the recited pore size provides unusual and unexpected results; and in the absence of a showing the recited pore size is not inventive over the prior art.

***Claim Objections***

8. Claims 9-13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Observation:

The specification at page 6, paragraph [0013] refers to “the 666 patent” without previously referring to the complete patent. Correction is respectfully requested.

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9. **The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Tech. Center 1600

